From: Chris G

Sent: Friday, March 6, 2020 8:58 AM PST

To: An, Je Hi; Greg Fiegel
CC: Virani, Jitendra
Subject: RE: Follow up from FDA

Dear Je Hi,

We are happy to provide a clearer description of our current activities in the marketplace. Following your email, we have reviewed and updated our website to better portray our current activities. The phrase "authorized service centers" is currently irrelevant, as there are no longer any third-party service centers in the USA (we have removed this language from our website). The majority of the servicing entities have been hospital service departments, in which repairs are done internal to the hospital system.

Rebotix Repair carries out two activities in the marketplace:

- Providing a repair component to hospitals to service their instruments, along with instructions and support
- Repair of hospital-owned instruments as a direct service provider to the healthcare institution

There is never any sale or resale of surgical instruments or any other medical device associated with our repair service. There is also never change of ownership. When instruments are repaired outside of the hospital itself, they are carefully tracked by serial number and returned to their original owners. Upon return, they pass through normal processes for similar incoming instruments that temporarily leave the hospital for sharpening, etc.

It is our belief that the original manufacturer, attempting to force a new instrument purchase, is no different than other similar manufacturers encouraging a purchase of new equipment over a repair. Hospitals commonly make safety and efficacy decisions about service operations on medical equipment they own, and we believe our repair service is no different.

We hope that this clarifies our activities and explains our position on why our repair services do not require a 510(k).

Sincerely,

Chris Gibson

Chief Operations Officer



539 Pasadena Avenue South St. Petersburg, FL 33707

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P: (727) 345-6362 F: (727) 343-4637 C: (813) 245-3974 www.rebotixrepair.com

From: An, Je Hi <Je.An@fda.hhs.gov> Sent: Friday, February 28, 2020 9:19 AM

To: Chris G <chris@rebotixrepair.com>; Greg Fiegel <GregFiegel@rebotixrepair.com>

Cc: Virani, Jitendra < Jitendra. Virani@fda.hhs.gov>

Subject: Follow up from FDA

Dear Chris,

This is a follow up our phone conversation with you on February 28, 2020. I also spoke on the phone on February 20, 2020 with Mr. Greg Fiegel and Mr. Joe Morrison regarding your company's activities and I wanted to follow up with you via email to summarize our conversation.

Your company states on your website www.rebotixrepair.com that your technology allows your authorized service centers to inspect and recondition instruments when the original manufacturers attempts to force a new purchase. Based on this information, we believe that a 510(k) is needed before you continue your operation.

You stated that you would provide further description of your activities (for example, inspection and recondition of instruments) and an explanation of why a 510(k) is not needed by March 6, 2020. Please confirm the receipt of this email.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.

Biomedical Engineer

Robotic Assisted Surgery Devices Team

DHT4A: Division of General Surgery Devices | OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality CDRH | Food and Drug Administration

Tel: 240-402-0018 JeHi.An@fda.hhs.gov

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